



**General Correspondence  
Comments on Proposed Rules:  
Expanded Access for Investigational Drugs for Treatment Use (2006N-0062)  
and Charging for Investigational Drugs (2006N-0061)**

March 12, 2007

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

**RE:**

**Docket No. 2006N-0062 Proposed Rule: Expanded Access to Investigational Drugs for Treatment Use and Docket No. 2006N-0061 Proposed Rule: Charging for Investigational Drugs**

Dear Sir/Madam:

Novo Nordisk Inc. appreciates the opportunity to provide comments to the Proposed Rules: *"Expanded Access to Investigational Drugs for Treatment Use"* and *"Charging for Investigational Drugs."* Novo Nordisk is a pioneer in biotechnology and a world leader in diabetes care and has a leading position within areas such as hemostasis management, growth hormone therapy, and hormone therapy for women. Novo Nordisk manufactures and markets pharmaceutical products and services that make a significant difference to our patients' lives, the medical profession and society.

Novo Nordisk fully supports FDA's goal to make experimental drugs more widely and easily available to seriously ill patients with no other treatment options. In providing expanded access of pharmaceutical agents to seriously ill patients in need, the main focus of FDA should be expediting and facilitating the initiation and completion of adequate and well controlled studies to acquire rigorous safety and efficacy data that will result in marketing approval of the agent. Generation of this data, clearly demonstrating the benefit of the drug for the indication, best helps the patient in need by clearly defining the treatment effect of the drug.

Further to the intent of the proposed revisions to the regulations, we believe there should be heightened oversight of FDA actions regarding the development of experimental therapeutic agents fitting these criteria. While there is benefit to expanding the access of these medications to seriously ill patients as there is no satisfactory alternative therapy, it is difficult to assess the

**Novo Nordisk Inc.**  
100 College Road West  
Princeton, NJ 08540  
609-987-5800 phone  
[www.novonordisk-us.com](http://www.novonordisk-us.com)

interference of access to these agents on drug development. The primary goal should be safeguarding the individual patient. While charging for the experimental drug could alleviate costs of the sponsor in development, it could delay obtaining the required data needed for approval. FDA should provide greater clarity and transparency for the approval of investigational protocols with the aim of facilitating timelier drug development resulting in greater access to life-saving medicines.

While we support the specific goal of making experimental drugs more widely available in appropriate situations we would like FDA to clarify the following aspect of the proposed rule:

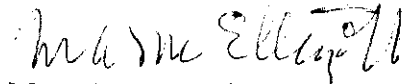
The proposed rule would give expanded access to individual patients, including in emergencies; intermediate-size patient populations; and larger populations under a treatment protocol or treatment investigational new drug application (IND). The distinction between the intermediate and larger populations is unclear in the proposed rule. While the intermediate population is defined as "in the range of ten to 100 patients," the larger population isn't described and this guideline should be clarified in the final rule.

In the proposed rule, FDA expresses concern that sponsors have used programs other than treatment INDs or treatment protocols to make investigational drugs available to large populations for treatment use, and in the future intends to evaluate whether proposals for open-label safety studies should be treatment INDs or treatment protocols that would have to meet the criteria in proposed 312.320. Open safety studies have an important role in elucidating the safety profile of an experimental drug prior to approval and there should not be consideration of converting these to treatment INDs or protocols. Additionally, the time required for formal review could impact expediting drug development.

In summary, Novo Nordisk supports FDA's efforts to clarify and streamline these processes and recommends heightened attention to FDA expediting activities and facilitating industry efforts to provide safe and efficacious agents to the public as quickly as safely possible. We look forward to your response and consideration of our comments.

Sincerely,

Novo Nordisk Inc.



Mary Ann McElligott, Ph.D.

Associate Vice President, Regulatory Affairs